

**REMARKS**

In response to the Office Action mailed February 27, 2007, Applicants submit the following remarks. The two-month extended deadline for filing a response is July 27, 2007. Applicants submit herewith a two-month Petition for Extension of Time and the appropriate fee. Applicants believe that this response is being timely filed and the fees submitted herein are sufficient. However, in the event that Applicants are incorrect in their assumption, please charge any necessary fees to Deposit Account No. 23-2415, referencing Docket No. 31747-705.201. Reconsideration of the subject application is respectfully requested.

In view of the remarks and amendments submitted herein, Applicants believe that the Application is in condition for allowance and such action is earnestly solicited.

The Office Action indicates that claims 3-5 are withdrawn as being drawn to non-elected invention. Applicants revised the claim listing to reflect the "withdrawn" status of claims 3-5. However, Applicants respectfully direct the Examiner's attention to the fact that claims 3-5 are readable on the elected species and depend from claim 2. The sequences listed in claims 3-5 all comprise the core amino acid sequence SEQ ID NO. 1: L-K-Q-N-G-G-N-F-S-L.

As set forth in MPEP 809.02(c) (B): "[w]hen a generic claim is subsequently found to be allowable, and not more than a reasonable number of additional species are claimed, treatment shall be as follows: (1) When all claims to each of the additional species are embraced by an allowable generic claim as provided by 37 CFR 1.141, applicant must be advised of the allowable generic claim and that claims drawn to the nonelected species are no longer withdrawn since they are fully embraced by the allowed generic claim."

Accordingly, Applicants expect that once Claim 2 is indicated as allowable, the Examiner will consider claims 3-5 which in turn should be indicated as allowable.

**Provisional Double Patenting**

Claims 2 and 6-12 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 3, 6, 10, 13, 15, 18 and 20 of co-pending Application No. 11/371,626.

Applicants respectfully request that the double patenting rejection be stayed in abeyance until the application is otherwise indicated as allowable. At such time, Applicants will submit a Terminal Disclaimer, if appropriate.

**Claim Rejection – 35 U.S.C. § 102**

Claims 2, and 6-7 were rejected under 35 U.S.C. 102(e) as allegedly being anticipated by Brooks et al. (U.S. Patent No. 7,122,635), hereinafter “the ‘635 patent.” This rejection is respectfully traversed for at least the following reasons.

A reference is only good for what it clearly and definitely discloses. As noted by the Federal Circuit, anticipation under 35 U.S.C. § 102 occurs only “when the same device or method, having all of the elements contained in the claim limitations, is described in a single prior art reference.” *Crown Operations International, Ltd. v. Solutia, Inc.*, 289 F.3d 1367 (Fed. Cir. 2002). “A single prior art reference anticipates a patent claim if it expressly or inherently describes each and every limitation set forth in the patent claim.” *Trintec Industries, Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292 (Fed. Cir. 2002). Moreover, the “single reference must describe the claimed invention with sufficient precision and detail to establish that the subject matter existed in the prior art.” *Verve, LLC v. Crane Cams, Inc.*, 311 F.3d 1116 (Fed. Cir. 2002). See also *In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990) (stating that “the reference must describe the applicant’s claimed invention sufficiently to have placed a person of ordinary skill in the field of the invention in possession of it.”); *PPG Indus., Inc. v. Guardian Indus., Corp.*, 75 F.3d 1558 (Fed. Cir. 1996) (“To anticipate a claim, a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter.”).

The Official Action appears to allege that the ‘635 patent anticipates the present claims based on inherency. It appears that the Examiner is taking the position that a denatured collagen type-IV selective peptide antagonist comprising a core amino acid sequence SEQ ID NO. 1: L-K-Q-N-G-G-N-F-S-L is an inherent characteristic of the antagonists disclosed in the ‘635 patent. It is respectfully submitted that the Official Action fails to meet the burden of proof required by the Patent Office for a rejection based on inherency as set forth in MPEP § 2112.

In setting the burden that must be met in a rejection based on anticipation by inherency the Patent Office provides the following guidance:

**IV. EXAMINER MUST PROVIDE RATIONALE OR EVIDENCE TENDING TO SHOW INHERENCY**

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted)

"In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art."

*Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). (See [www.uspto.gov/web/offices/pac/mpep/documents/2100\\_2112.htm#sect2112](http://www.uspto.gov/web/offices/pac/mpep/documents/2100_2112.htm#sect2112))

Here the Official Action provides no rationale or evidence to show that antagonists disclosed in the '635 patent inherently comprise a core amino acid sequence SEQ ID NO. 1: L-K-Q-N-G-G-N-F-S-L. It would appear that the Official Action asserts that the present antagonists are species that are anticipated by a genus disclosed in the '635 patent. However, the Office Action does not meet the requirements set forth in MPEP 2131.02 for "Genus-Species Situations." As set forth in the MPEP:

"[w]hen the compound is not specifically named, but instead it is necessary to select portions of teachings within a reference and combine them, e.g., select various substituents from a list of alternatives given for placement at specific sites on a

generic chemical formula to arrive at a specific composition, anticipation can only be found if the classes of substituents are sufficiently limited or well delineated."

Ex parte A, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990). If one of ordinary skill in the art is able to "at once envisage" the specific compound within the generic chemical formula, the compound is anticipated. One of ordinary skill in the art must be able to draw the structural formula or write the name of each of the compounds included in the generic formula before any of the compounds can be "at once envisaged." One may look to the preferred embodiments to determine which compounds can be anticipated. In re Petering, 301 F.2d 676, 133 USPQ 275 (CCPA 1962).

Here the Office Action offers no evidence or reasoning to show that one of ordinary skill in the art is able to "at once envisage" the specific compound comprising a core amino acid sequence SEQ ID NO. 1: L-K-Q-N-G-G-N-F-S-L within a generic chemical formula, assertedly disclosed in the '635 patent.

Accordingly, withdrawal of the '102 rejection based on the '635 patent is in order and is respectfully requested.

**CONCLUSION**

In view of the remarks and amendments submitted herein, Applicants believe that the Application is in condition for allowance and such action is earnestly solicited.

If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (858) 350-2337.

Respectfully submitted,

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Dated: July 27, 2007

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